



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

1733 5 JUN 22 P2:18

JUN 14 2005

Mr. Robert S. Rister  
Consultant to Organix South, Inc.  
6290-B 147<sup>th</sup> Avenue North  
Clearwater, Florida 33760

Dear Mr. Rister:

This is in response to your letter of April 22, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statements, among others, will be made for the product Narsimha: "Heart Cholesterol Support" and "[S]upport healthy LDL...levels...."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claims you are making for this product represent that the product is intended to affect blood cholesterol but do not also include statements about it being intended to affect blood cholesterol that is already in the normal range, they are implied disease claims.

Your product label also contains the statements "[H]elping the arteries remain flexible" and "[K]eeps the white blood cells known as granulocytes from upsetting balance in the lining of the arteries." In light of the claims made about cholesterol and heart health, these claims are implied disease claims in that they imply the product will also prevent coronary heart disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended

97S 0163 LET 832

Page 2 - Mr. Robert S. Rister

for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

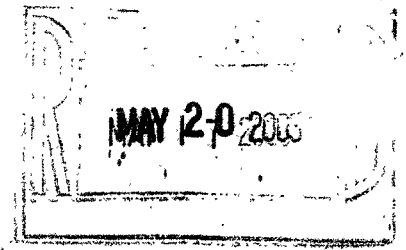
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Florida District Office, Office of Compliance, HFR-SE240

91673

Organix-South, Inc.  
6290-B 147th Avenue North  
Clearwater, FL 33760

Phone: 727-531-8801  
Fax: 727-531-8807  
Email: Rob@organixsouth.com



April 22, 2005

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204

NOTICE OF DESCRIPTIVE CLAIMS

Enclosed herewith are texts of descriptive claims made by Organix South on or after  
April 22, 2005:

AJAY  
ANITA  
KAMA  
MANISH  
NARSIMHA  
NARTANA  
NEEM  
NIRMAL  
NISHA  
PAVAN  
SAHANA  
THERA NEEM  
THERA NEEM LEAF  
USHA  
VIJAY

Text of statement, name of supplement, identification of manufacturer, and contact  
information for each product are included on its sheet. I certify that these exhibits are  
accurate copies of the originals and that the firm has acquired substantiation that statements  
therein are truthful and not misleading.

Sincerely,

Robert S. Rister  
Consultant to Organix South, Inc.

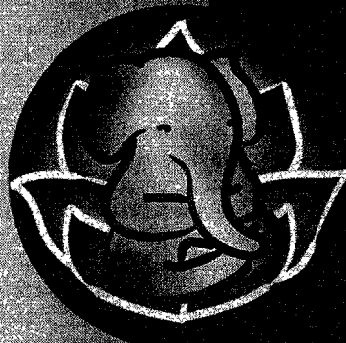
#1203

# Narsimha

Heart Cholesterol  
Support \*

**Thera  
Veda**

**SUPERCritical  
TECHNOLOGY**  
INSPIRED BY  
**AYURVEDIC  
WISDOM**



# Narsimha

Heart Cholesterol  
Support \*

DIE LARY SUPPLEMENT

PATENT PENDING  
WHOLE HERB TECHNOLOGY

60  
SUPERCritical  
VEGETARIAN  
CAPSULES

Wheresoever  
you go,  
go with all  
your heart,  
- Chinese  
Proverb



**Supercritical Whole Herb Technology**  
TheraVeda supplements provide the benefits of chemical-free herbal extracts and natural whole herbs through an innovative, patent-pending technology that uses no harmful chemical solvents. Supercritical extraction is a natural process that makes powerful herbal extracts containing the broadest spectrum of an herb's essential nutrients. Our unique technology concentrates the supercritical extract with the post-supercritical extract. This is then combined with the whole herb in a vegetarian capsule, achieving the broad spectrum previously only available with whole herb supplements, but now in a concentrated extract formula.\*

**TheraVeda's Narsimha Formula** was developed using unique herbs to support the heart by maintaining lipid metabolism and promoting healthy cholesterol levels.\*

Organic-South's TheraVeda™ vegetarian capsules contain NO corn, soy, salt, yeast, sugar, wheat, egg or dairy products and are formulated without the use of preservatives, artificial flavors or colors. Our premium vegetarian capsules are prepared without any chemical solvents and are independently verified to be free of pesticides and harmful levels of heavy metal contaminants.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

**Thera  
Veda**

Formulated &  
distributed by:

Organic-South, Inc.,  
Clearwater, FL 33760

www.theravedaherbs.com  
1-888-989-0536

*Narsimha, in the Indian language, means the Lion Among Men, or LIONHEARTED.*

*Commiphora mukul*, also known as guggul or guggulu, is a resin collected from the bark of the nvrh tree. The "guggulipid" extracted from the herb is widely reported to support healthy LDL and HDL levels, helping the arteries remain flexible. Turmeric is a source of the antioxidant curcumin. Exactly how curcumin affects circulation is not entirely understood, but scientists theorize that it keeps the white blood cells known as granulocytes from upsetting balance in the lining of the arteries. *Tinospora* is a bitter, stimulating good digestion - thorough digestion of food shortens the time bloodstream concentrations of fats are elevated after a meal of fatty foods. Defatted fenugreek supports proper fluid levels without depleting minerals, and provides beneficial fibers, helping to prevent fat accumulation.\*

Ayurveda teaches that any heart can benefit from a calm, orderly, planned lifestyle. Avoiding heavy meals, getting a good night's sleep, and patiently dealing with stress will make any heart work better.\*

## Supplement Facts

Serving size: 2 capsules  
Serving per container: 30

Amount Per Serving	% Daily Value
Commiphora mukul SCO2 extract (1:100)	10 mg •
Commiphora mukul PSE** hydrophilic extract (min 2.5% guggulsterones E&Z 2.5 mg)	90 mg •
Turmeric (rhizome) SCO2 extract (55% turmerone 55 mg & 11% curcuminoids 11 mg)	100 mg •
Tinospora cardifolia (stem) SCO2 extract (70:1) 20 mg	•
Tinospora cardifolia (stem) PSE** hydrophilic extract (2% bitters 3 mg)	150 mg •
Defatted Fenugreek (seed) powder	480 mg •

\* Daily Value not established.

100% Natural, Vegan, Vegetarian  
(No animal products, no honey, no gelatin)

100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients

100% Natural, No animal ingredients  
100% Natural, No animal ingredients